

ORAL ARGUMENT NOT SCHEDULED

No. 25-1140

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

IN RE IOWASKA CHURCH OF HEALING, Petitioner

ON PETITION FOR A WRIT OF MANDAMUS TO PAMELA J.
BONDI, ATTORNEY GENERAL, AND U.S. DRUG ENFORCEMENT
ADMINISTRATION

OPPOSITION TO PETITION FOR A WRIT OF MANDAMUS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

(A) Parties, Intervenors, and Amici

Petitioner is the Iowaska Church of Healing (Iowaska). Respondents are the Honorable Pamela Bondi, in her official capacity as Attorney General of the United States, and the U.S. Drug Enforcement Administration (DEA). There are no intervenors or amici as of this time.

(B) Ruling under Review

The Petition for Mandamus seeks an order compelling the Attorney General and/or DEA to issue a final decision on Iowaska's request for a religious exemption to the Controlled Substances Act within 21 days of this Court's ruling on the Petition.

(C) Related Cases

Counsel are not aware of any related cases within the meaning of this Court's rules. This Court affirmed the district court's denial of Iowaska's request for tax-exempt status in *Iowaska Church of Healing v. Werfel*, 105 F.4th 402 (D.C. Cir. 2024).

s/s Lowell V. Sturgill Jr.
Lowell V. Sturgill Jr.

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GLOSSARY

APA	Administrative Procedure Act
App.	Appendix to Petition for Mandamus
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
DMT	Dimethyltryptamine
RFRA	Religious Freedom Restoration Act

Introduction

Mandamus is a “drastic remedy reserved for extraordinary circumstances.” *In re National Nurses United*, 47 F.4th 746, 752-753 (D.C. Cir. 2022). Mandamus is available only where (1) a petitioner demonstrates that an agency has a “crystal-clear legal duty to act,” *id.* at 752; (2) the petitioner “has no other adequate means to attain the relief it desires,” *In re Center for Biological Diversity*, 53 F.4th 665, 670 (D.C. Cir. 2022) (quoting *In re Core Commc’ns, Inc.*, 531 F.3d 849, 860 (D.C. Cir. 2008); and (3) the agency’s delay in fulfilling that duty is “egregious,” *National Nurses*, 47 F.4th at 753 (quoting *Telecommunications Rsch. & Action Ctr. v. FCC (TRAC)*, 750 F.2d 70, 79 (D.C. Cir. 1984)). Iowaska Church of Healing (Iowaska) can meet none of those conditions. The petition should be denied.

The petition fails at the outset because the U.S. Drug Enforcement Administration (DEA) does not have a statutory or other duty to resolve Iowaska’s religious-exemption request by any particular date. *See National Nurses*, 47 F.4th at 752. Congress has not established a deadline by which DEA must issue a final decision on a petition for a religious exemption to the Controlled Substances Act. In addition, DEA

has reserved discretion to issue a final decision on a religious-exemption request until after the petition, along with all submissions DEA deems necessary, has been fully evaluated. *See Diversion Control Div., DEA, Guidance Regarding Petitions for Religious Exemption from the Controlled Substances Act Pursuant to the Religious Freedom Restoration Act (Revised)* (updated Nov. 20, 2020), <https://perma.cc/VE74-SQMH> (DEA Guidance). Because DEA does not have a crystal-clear duty to issue a final decision on Iowaska's religious-exemption request by the time Iowaska demands here (21 days from a final ruling on the mandamus petition), Iowaska's mandamus petition can be denied without further inquiry, as in *National Nurses*.

Although the Court need not reach this issue, Iowaska's request for mandamus also fails because Iowaska has alternative means to attain an expedited ruling on its exemption request and because Iowaska cannot show compelling equitable grounds for mandamus. Iowaska could file a district court action under the Administrative Procedure Act (APA) seeking to "compel agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1), or a suit requiring similar relief under the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb-1. And

Iowaska has failed to identify compelling equitable grounds justifying the extraordinary remedy of mandamus. Ayahuasca contains N-Dimethyltryptamine (DMT), an exceptionally dangerous Schedule I controlled substance. Thus, any religious exemption would need to be carefully crafted to ensure that the ayahuasca material Iowaska wants to import is (1) fully accounted for, (2) distributed only to adult members of Iowaska, and (3) properly disposed of if any is left unused. DEA also would need to ensure that Iowaska members have access to medical care while taking ayahuasca and that the ayahuasca is not lost nor stolen.

DEA has worked diligently to evaluate Iowaska's exemption request, participating in multiple meetings with Iowaska personnel, conducting a site visit to a planned storage facility, and evaluating additional information Iowaska has provided. DEA continues to scrutinize Iowaska's exemption request with the very limited staff available while also attending to other important responsibilities, which include recently granting two other requests for religious exemptions. Moreover, Iowaska itself substantially delayed the review process by focusing on its attempt to obtain 501(c)(3) status rather than on timely responding to a request by DEA for additional pertinent information.

An agency has discretion to schedule its work to prioritize matters that best fit the agency's overall responsibilities, and courts should respect the realities of limited agency staffing. *See National Nurses*, 47 F.4th at 757. DEA has made substantial progress toward a final decision on Iowaska's religious-exemption request and is in the later stages of that process. Especially given the significant health and safety issues ayahuasca use presents, this Court should permit DEA to finish the full review that is appropriate here.

Statement of the Case

A. Statutory and Regulatory Background

1. The Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236, creates a comprehensive federal scheme regulating the handling of controlled substances. *See Gonzales v. Raich*, 545 U.S. 1, 10, 12-13 (2005). Title II of that Act contains statutory provisions known as the Controlled Substances Act (CSA), which establish a “closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.” *Id.* at 12-13.

Subchapter I of the CSA provides the Attorney General regulatory and enforcement authority over controlled substances and their handling, including authority to determine who may manufacture, distribute, dispense, or possess any controlled substance and in what manner. *See, e.g.*, 21 U.S.C. §§ 811, 822-824, 831, 841. The CSA also grants the Attorney General authority to “promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.” *Id.* § 821; *see also id.* § 871(b) (providing that “[t]he Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter”). The Attorney General has delegated this authority to DEA, *see* 28 C.F.R. § 0.100, and DEA has promulgated regulations related to controlled substances, *see* 21 C.F.R. pts. 1300-1316.

The CSA establishes five schedules of controlled substances. *See* 21 U.S.C. § 812. Schedule I regulates substances with “a high potential for abuse” and “no currently accepted medical use in treatment in the United States,” and concerning which “[t]here is a lack of accepted safety for use . . . under medical supervision.” *Id.* § 812(b)(1). The controlled substance

at issue here (DMT) falls under Schedule I of the CSA. *See id.* § 812(a), (b)(1), (c), sched. I(c)(6). That section applies to “any material, compound, mixture, or preparation[] which contains any quantity” of this substance. *Id.* § 812(c)(5). Ayahuasca—the drug Iowaska seeks permission to import, possess, and distribute—contains the Schedule I controlled substance DMT, which is “exceptionally dangerous.” *Gonzales v. O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 432 (2006).

2. The CSA authorizes the Attorney General to register an applicant to manufacture or distribute a Schedule I controlled substance where, among other requirements, the registrant maintains effective controls against diversion of that substance into other than legitimate medical, scientific, research, or industrial channels. *See* 21 U.S.C. § 823(a)-(b). The CSA also authorizes the Attorney General to waive, by regulation, the registration requirement for certain manufacturers, distributors, or dispensers if he finds that consistent with the public interest. *See id.* § 822(d).

In deciding whether to register an applicant to manufacture or distribute a Schedule I controlled substance, DEA considers whether the requested registration is consistent with the public interest. *See* 21

U.S.C. § 823(a)-(b). To evaluate the public interest, DEA considers various factors, including “(1) the need to maintain effective control against diversion of the controlled substances into non-legitimate channels; (2) the applicant’s compliance with applicable state and local law regarding use of the controlled substance; (3) whether the applicant has any prior convictions relating to controlled-substance manufacture, distribution, or dispensing; (4) the applicant’s past experience in manufacturing controlled substances; and (5) other factors that ‘may be relevant to and consistent with the public health and safety.’” *Soul Quest of Mother Earth, Inc. v. Attorney Gen., U.S.*, 92 F.4th 953, 958 (11th Cir. 2023) (quoting 21 U.S.C. § 823(a)). “If the application is approved, the applicant will be granted a Certificate of Registration authorizing it to ‘possess, manufacture, distribute, or dispense controlled substances . . . to the extent authorized by [its] registration and in conformity with the CSA.’” *Id.* (alterations in original) (citing 21 U.S.C. § 822(b)).

3. Prior to the Supreme Court’s decision in *O Centro*, no process existed by which an individual who wished to use ayahuasca (or any controlled substance other than peyote, *see* 21 C.F.R. § 1307.31) for religious purposes could obtain permission to do so under the CSA.

O Centro held that RFRA, 42 U.S.C. § 2000bb *et seq.*, requires DEA to provide individualized consideration to requests for religious exemptions to the CSA. *See* 546 U.S. at 437. RFRA provides that the “[g]overnment shall not substantially burden a person’s exercise of religion” unless the government can demonstrate that “application of the burden to the person . . . is in furtherance of a compelling governmental interest and . . . is the least restrictive means of furthering that compelling governmental interest.” 42 U.S.C. § 2000bb-1(a)(b).

In compliance with *O Centro*, DEA created a petition process for seeking RFRA exemptions from the CSA. *See Soul Quest*, 92 F.4th at 958-959. That process is available to anyone who wishes to manufacture, distribute, import, export, use, or possess ayahuasca or any other controlled substance for religious purposes. *See* DEA Guidance.

The DEA Guidance explains that all petitions for exemption from the CSA under RFRA should be submitted in writing or e-mail to the Assistant Administrator, Diversion Control Division, DEA in Springfield, Virginia. DEA Guidance 1. A petition may include both a written statement and supporting documents and should provide as much information as the petitioner deems necessary to demonstrate that the

application of the CSA to the party's activity would impose a substantial burden on the petitioner's sincere exercise of religion. *See id.*

The petition should include “detailed information about, among other things, (1) the nature of the religion (*e.g.*, its history, belief system, structure, practice, membership policies, rituals, holidays, organization, leadership etc.; (2) each specific religious practice that involves the manufacture, distribution, dispensing, importation, exportation, use or possession of a controlled substance; (3) the specific controlled substance that the party wishes to use; and (4) the amounts, conditions, and locations of its anticipated manufacture, distribution, dispensing, importation, exportation, use or possession.” DEA Guidance 1-2. A petitioner “is not limited to the topics outlined above,” and may submit any information the petitioner deems relevant. *Id.* at 2.

The Guidance also explains that DEA “may require a petitioner to submit such additional documents or written statements of facts relevant to the petition as DEA deems necessary to determine whether the petition should be granted.” DEA Guidance 2. The Guidance notes that “[i]t is the petitioner's responsibility to provide DEA with accurate contact information,” and that “[i]f a petitioner does not respond to a

request for additional information within 60 days from the date of DEA's request, the petition will be considered to be withdrawn." *Id.*

The Guidance cautions that even where a petition for a religious exemption from the CSA is granted, the petitioner "remains bound by all applicable laws and [CSA] regulations governing registration, labeling and packaging, quotas, recordkeeping and reporting, security and storage, and periodic inspections, among other things." DEA Guidance 2 (citing 21 C.F.R. pts. 1300-1316). As the Guidance explains, however, "a petitioner who seeks exemption from applicable CSA regulations (as opposed to the CSA itself)" may petition for an exemption from "each regulation from which the petitioner seeks exemption" "under 21 C.F.R. § 1307.03." *Id.*

The Guidance explains that "[a]fter the filed petition—along with all submissions in response to any requests for additional information—has been fully evaluated, the Assistant Administrator of the Diversion Control Division shall provide a written response that either grants or denies the petition." DEA Guidance 2. The Guidance also advises that "[n]o petitioner may engage in any activity prohibited under the [CSA]

unless the petition has been granted and the petitioner has applied for and received a DEA Certificate of Registration.” *Id.*

B. Iowaska’s Religious-Exemption Request

1. Petition for a Religious Exemption

By letter of February 28, 2019, Iowaska submitted its petition for a religious exception to DEA’s Diversion Control Division. *See* App. C001. The letter noted that Iowaska was not yet “fully operational” but was “preparing to offer religious services that will provide the Sacrament of Ayahuasca in tea form to its members.” *Id.* The letter also recited that Iowaska was requesting a “plenary exemption” to the “entirety” of 21 C.F.R. Chapter II, but that because ayahuasca “contains DMT at an increased level of bioavailability once its ingredients are combined,” Iowaska “desires to address and comply with any regulatory requirements that may apply.” App. C002.

Over the next several months, counsel for Iowaska e-mailed DEA periodically to check on the status of its petition. *See* App. C155-C179. Each time, DEA promptly responded. *See id.* DEA also advised Iowaska that DEA’s response to Iowaska’s petition might take some time because

the Diversion Control Office had “several RFRA requests along with many other policy questions” to address. App. C160.

2. Request for Additional Information

On February 14, 2022, DEA requested additional information regarding Iowaska’s religious-exemption request, addressing issues presented by the materials Iowaska provided to support its petition. *See* App. C182-C185. Those questions all pertained to DEA’s statutory obligation to minimize diversion and safety risks presented by the use of Schedule I controlled substances. *See* App. C183.¹

Counsel for Iowaska acknowledged receipt of DEA’s letter on February 21, 2022. *See* App. C188. On January 31, 2023, however, Iowaska notified DEA that Iowaska was focusing its efforts on pending litigation against the United States to secure tax-exempt status and that

¹ The questions included where Iowaska plans to store, distribute, and dispense ayahuasca; whether Iowaska plans to dispense ayahuasca at other events outside “regular worship services”; and the proposed source of the imported materials, the estimated quantity to be imported the first year, who will have access to the stored materials, and where and by whom the tea will be prepared and where and how it will be stored. App. C183. DEA also asked Iowaska to explain, among other things, how it planned to dispose of any unused or expired tea, what protocols are planned to ensure minors will not have access to the controlled substance, and how Iowaska planned to handle any medical emergency that might arise. *See* App. C184.

it would “return its focus to [DEA’s] letter” “[o]nce this litigation has concluded.” App. C190.

Under the DEA Guidance document discussed above, Iowaska’s failure to respond to DEA’s request for additional information within 60 days of February 14, 2022, would have been grounds for DEA to consider the petition constructively withdrawn. *See supra* pp. 9-10. DEA took no such action, however.

3. Meeting and Additional Requests for Information

DEA met with Iowaska’s counsel and leadership on June 13, 2023. *See* App. C192-C193. On July 12, 2023, DEA notified Iowaska that it was reviewing the information Iowaska provided after that meeting to see if any additional information was necessary. *See* App. C203. On November 27, 2023, DEA requested further clarification on some of the questions and answers from the June 13, 2023, interview. *See* App. C205.² Iowaska

² Those questions included “what controlled substances activities (i.e., import, manufacture, distribution . . .) will occur at any location(s) confirmed by [Iowaska] from the time of receipt to ultimate use or disposal of the controlled substance.” App. C205 (ellipsis in original). DEA also asked Iowaska to identify its anticipated sources of supply for any domestic and international suppliers of the controlled substance, the intended methods of transport for any domestic or international shipments, whether Iowaska has any record-keeping systems in place so

provided answers to those inquiries on January 22, 2024. *See* App. C206-C212.

On May 1, 2024, Iowaska requested an update on the status of its petition for a CSA exemption, attaching a settlement agreement through which DEA decided to allow another religious entity (the Church of the Eagle and Condor) to use ayahwasca for religious purposes. *See* App. C213-C233. DEA responded promptly, *see* App. C234, and on May 21, 2024, DEA proposed a conference call with DEA headquarters, *see* App. C235. During that call, which was held two days later, DEA identified certain additional information needed to resolve Iowaska's exemption request and eligibility for DEA registration. That information included a physical assessment of recordkeeping measures in place, an inspection of the security system for the areas where controlled substances will be handled and stored, and clarification on Iowaska's fee policies. *See* Mandamus Pet. 12-13.

DEA can evaluate the adequacy of Iowaska's diversion-control methods, and how many members approximately Iowaska intends to have. *See id.*

4. Site Visit and Follow-Up Request for Information

On July 3, 2024, Iowaska notified DEA that it had secured a property to serve as its registered location, and it requested an on-site inspection by DEA. *See* App. C237. The inspection was conducted on July 24, 2024. *See* App. C238. DEA requested additional information during that visit, *see* App. C239, and on the following day provided Iowaska with a form to document the destruction or disposal of controlled substances, *see id.* Iowaska provided the additional information requested in two separate e-mails on July 26, 2024, and August 2, 2024. *See* App. C240.

On August 23, 2024, DEA advised Iowaska that it had provided its on-site inspection report and other materials to DEA headquarters for review. *See* App. C252. On September 27, 2024, DEA advised that it was not possible to provide a date certain by which its review would be completed because the agency has finite resources and numerous matters to review. *See* App. C255. In November of 2024 and January of 2025, DEA advised Iowaska that its exemption request was still under review. *See* App. C257-C258, C266-C274. Iowaska's exemption request remains actively under review as of the present time.

Argument

DEA Has Not Unreasonably Delayed in Deciding Whether To Grant Iowa's Petition for a Religious Exemption, and Mandamus Is Not Warranted in Any Event.

“When a party requests a writ of mandamus against an agency under the All Writs Act, [this Court] undertake[s] a three-step inquiry.” *In re National Nurses United*, 47 F.4th 746, 752 (D.C. Cir. 2022) (quoting 28 U.S.C. § 1651(a)). First, the Court must ensure it has jurisdiction, as to which there is no dispute in this case. *Id.* at 752-53. Second, the Court “must consider whether the agency has a crystal-clear legal duty to act.” *Id.* at 752. “The writ remains reserved only for the most transparent violations of a clear duty to act” and is not available for matters “within the agency’s discretion.” *Id.* (cleaned up). Third, the Court “consider[s] whether judicial intervention would be appropriate” given that “the writ of mandamus is a drastic remedy reserved for extraordinary circumstances.” *Id.* at 752-53. In cases of alleged agency delay, this Court will not issue the writ unless the agency’s delay in fulfilling its duty is “egregious.” *Id.* at 753 (quoting *TRAC*, 750 F.2d at 79). Iowa’s petition falls short under both the second and third prongs of this inquiry.

A. DEA Has Not Violated Any Legal Duty To Act on Iowaska's Religious Exemption Request by the Date the Mandamus Petition Demands.

In assessing whether an agency has violated a clear legal duty, this Court “look[s] to the statutory requirements imposed by Congress and whether an Executive Branch agency retains discretion over a particular action.” *National Nurses*, 47 F.4th at 752. Iowaska's mandamus petition fails on both aspects of that analysis.

To begin, Congress has not mandated any deadline by which DEA must rule on an administrative request for a religious exemption to the CSA. Iowaska concedes that “[n]either CSA nor RFRA sets an explicit timetable for religious exemption determinations.” Pet. 27. This case is thus unlike those in which this Court granted mandamus relief in response to an agency's failure to comply with a statutory deadline. *See, e.g., In re: Center for Biological Diversity*, 53 F.4th 665, 669 (D.C. Cir. 2022); *In re: Public Emps. for Env't Resp.*, 957 F.3d 267, 269 (D.C. Cir. 2020); *In re: Bluewater Network*, 234 F.3d 1305, 1309 (D.C. Cir. 2000). Nor does any DEA regulation or guidance prescribe a time by which DEA must act on a petition for an exemption from the CSA.

DEA retains discretion regarding the process and timing of its consideration and resolution of requests for religious exemptions. DEA's Guidance memorandum states that DEA "may require a petitioner to submit such additional documents or written statements of facts relevant to the petition *as DEA deems necessary to determine whether the petition should be granted.*" DEA Guidance 2 (emphasis added). And the memorandum also states that DEA "shall provide a written response that either grants or denies the petition" only "[a]fter the filed petition—along with all submissions in response to any requests for additional information—has been fully evaluated," *id.* (emphasis added)—imposing no deadline for a final decision on the request.

"Writs of mandamus are reserved for 'the ordering of a precise, definite act about which an official ha[s] no discretion whatever.'" *National Nurses*, 47 F.4th at 757 (quoting *Norton v. Southern Utah Wilderness All.*, 542 U.S. 55, 63 (2004) (cleaned up)). The lack of statutory or regulatory deadlines and DEA's reservation of discretion to fully consider a religious exemption request confirms that DEA has violated no clear legal duty by taking the time needed to fully evaluate Iowaska's religious-exemption request.

B. Iowaska Has Not Identified Extraordinary Circumstances Justifying Mandamus Relief.

“Violating a clear duty . . . is just the beginning of the mandamus analysis.” *Center for Biological Diversity*, 53 F.4th at 670. A mandamus petitioner must also show that it “has no other adequate means to attain the relief it desires,” *id.* (quoting *Core Commc’ns*, 531 F.3d at 860, and must demonstrate “compelling equitable grounds” for mandamus, *id.* (quoting *In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10 (D.C. Cir. 2005)). Iowaska can make neither showing.

1. Iowaska Has Other Adequate Means to Attain the Relief it Desires.

As Iowaska (Pet. 18) observes, the APA authorizes a court to “compel agency action unlawfully withheld or unreasonably delayed.” 5 U.S.C. § 706(1). That APA section does not provide a clear duty for the agency to act by a particular date, but it would provide a statutory basis for filing an action in district court arguing that the delay here is unreasonable. Iowaska has identified no reason why an APA suit under section 706(1) would not provide an adequate means of seeking the relief the mandamus petition demands.

Iowaska also could bring a district court suit to compel DEA to act on its religious-exception request under RFRA, which provides “a claim or defense to persons whose religious exercise is substantially burdened by government.” 42 U.S.C. § 2000bb(b)(2); *see also id.* § 2000bb-1(c). Iowaska demurs, contending that DEA “has successfully argued that at least while an exemption application is pending, it is for DEA, not the courts, to apply RFRA’s strict scrutiny test in the first instance.” Pet. 2 (citing *Soul Quest Church of Mother Earth, Inc. v. Attorney Gen. U.S.*, 92 F.4th 953, 965-71 (11th Cir. 2023)). Iowaska is incorrect about DEA’s argument in *Soul Quest* and the court’s holding in that case.

Soul Quest filed an administrative petition requesting that DEA grant a religious exemption to the CSA for its planned use of ayahuasca. It also filed a district court suit seeking the same relief under RFRA, and that suit remained pending at the time DEA denied the entity’s exemption request. At that point, instead of filing a timely petition for review from DEA’s denial of the administrative petition as authorized by 21 U.S.C. § 877, Soul Quest amended its complaint to challenge the denial. *See Soul Quest*, 94 F.4th at 956.

The district court in *Soul Quest* dismissed the complaint because 21 U.S.C. § 877 vests the courts of appeals with exclusive jurisdiction to review final DEA decisions, and the Eleventh Circuit affirmed. *See* 92 F.4th at 972. Contrary to what Iowaska contends here, DEA did not argue, and the Eleventh Circuit did not hold, that *Soul Quest*'s filing of an administrative petition with DEA precluded it from filing its district court RFRA action. Rather, DEA argued, and the Eleventh Circuit held, that once DEA denied the administrative petition, judicial review of all issues related to the entity's request for a religious exemption was available exclusively in the Eleventh Circuit. *See id.* at 965-72.

That conclusion is consistent with this Court's decisions, *see Hemp Indus. Ass'n v. DEA*, 36 F.4th 278 (D.C. Cir. 2022); *John Doe, Inc. v. DEA*, 484 F.3d 561 (D.C. Cir. 2007), and there is no circuit split on this issue, *cf.* Pet. 23. A plaintiff may file a district court action under RFRA seeking a religious exemption from the CSA without exhausting administrative remedies. *See Oklevueha Native Am. Church of Hawaii, Inc. v. Holder*, 676 F.3d 829 (9th Cir. 2012).³

³ To the extent the district court in *Van Kush v. DEA*, Civ. No. 20-0906, 2022 WL 1978730, *3 (D.D.C. June 6, 2022), held the contrary, the court's holding was erroneous in that respect.

2. Iowaska Has Not Demonstrated Compelling Equitable Grounds for Mandamus.

Because Iowaska has failed to show that DEA violated a clear legal duty or that mandamus is the only means of seeking an expedited decision on its religious-exemption request, this Court need not address whether Iowaska has demonstrated compelling equitable grounds for relief. But Iowaska in any event fails to make that showing. DEA has timely responded to Iowaska's requests for updates on the status of its religious-exemption request and reasonably requested additional information that the agency is still evaluating. The issues are complex and the stakes high, since ayahuasca contains DMT, an "exceptionally dangerous" Schedule I controlled substance. *Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 432 (2006). Consideration of the *TRAC* factors thus confirms that Iowaska has failed to meet its burden on this issue. *See Center for Biological Diversity*, 53 F.4th at 670.

The first and second *TRAC* factors consider the timeline for agency review, asking "whether Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute" and directing that "the time agencies take to make

decisions must be governed by a ‘rule of reason.’” 750 F.2d at 80. There is no dispute that “[n]either CSA nor RFRA sets an explicit timetable for religious exemption determinations.” Pet. 27. And DEA’s handling of Iowaska’s request is reasonable in light of the complexity of the public health issues Iowaska’s religious-exemption request raises, the danger of the Schedule I substance it plans to dispense, and DEA’s need to allocate limited resources across numerous exemption requests and policy matters.

DEA has timely responded to each status request Iowaska made, participated in multiple in-person and other meetings with Iowaska personnel, and conducted a site visit at Iowaska’s request. And the agency continues to evaluate supplemental information it requested from Iowaska that is plainly pertinent to the exemption inquiry. *See supra* pp. 11-15.

Iowaska’s own actions further undermine its contention that DEA has acted unreasonably by not timely resolving Iowaska’s religious-exemption request. At the time it submitted its request, Iowaska advised DEA that the Church was “not yet fully operational” and planned to start offering ayahuasca to its members at some unspecified date in the future.

App. C001. When DEA was able to address the request, it met with Iowaska representatives and requested additional information. *See supra* p. 12.

At that point, almost a year elapsed before Iowaska informed DEA that it was focusing on litigating its section 501(c)(3) tax case and would provide the requested information later. *See* App. C190. That delay would have provided grounds for DEA to consider the religious-exemption request withdrawn. *See* DEA Guidance 2. DEA took no such action, however, and continued to evaluate Iowaska's religious-exemption request, participating in additional meetings with Iowaska, conducting a site visit at Iowaska's request, and asking for and evaluating additional relevant information and materials. *See supra* pp. 13-15.

During this period, DEA has also needed to allocate agency resources to the press of matters, including the adjudication of two other religious-exemption requests that DEA ultimately granted. *See supra* pp. 11-12; Pet. 16-17. This Court has recognized that "agencies have discretion to prioritize in light of the [Administrator's]. . . assessments whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular

enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all." *National Nurses*, 47 F.4th at 757 (citations and internal quotation marks omitted). DEA reasonably exercised such discretion in allocating finite resources to address other pending matters, including multiple other religious-exemption requests.

Iowaska complains about DEA's grant of other exemptions, *see* Pet. 16-17, but DEA's action on those requests confirms that DEA takes these requests seriously and grants them when the public interest allows. DEA's work on those requests also confirms that a request for an exemption from the CSA for the use of Controlled I substances is complex and far from the "simple[] task," Pet. 26, or light lift, Pet. 29, Iowaska suggests.

DEA's recent settlement agreement with Church of the Eagle and Condor, *see* App. C217, is instructive. That agreement contains fifteen single-spaced pages covering issues similar to those DEA has raised with Iowaska. Those matters include detailed requirements governing the Church's importation, manufacture, distribution, storage, and disposal of ayahuasca; requirements concerning the Church's obligation to provide

effective controls and procedures to guard against theft and diversion; and rules regarding record-keeping. *See* App. C220-C228.

Contrary to what Iowaska suggests (Pet. 29-30), those requirements cannot simply be cut-and-pasted into a religious exemption for Iowaska or any other requester. DEA must investigate each religious-exemption request to determine what measures are necessary to protect public health and safety and whether the requester can be trusted to carry out those requirements. *See O Centro*, 546 U.S. at 431 (noting that “strict scrutiny,” which RFRA adopts for laws that substantially burden the exercise of religion, “does take ‘relevant differences’ into account,” quoting *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 228 (1995)).

For the same reasons, Iowaska incorrectly argues that DEA’s task here is simply to “apply a clear legal standard to a single entity. Pet. 29. Analysis under RFRA is inherently fact-specific. *See, e.g., United States v. Christie*, 825 F.3d 1048, 1062 (9th Cir. 2016); *Tagore v. United States*, 735 F.3d 324, 332 (5th Cir. 2013), abrogated on other grounds by *Groff v. DeJoy*, 600 U.S. 447 (2023); *cf. Levitan v. Ashcroft*, 281 F.3d 1313, 1318 (D.C. Cir. 2002) (addressing Free Exercise Clause rights).

Evaluating Iowaska's RFRA-based request for a religious exemption requires DEA to make detailed factual determinations and sensitive policy judgments regarding whether, and under what conditions, a person or entity requesting a religious exemption from the CSA should be allowed to import, use, and distribute Controlled I substances consistent with public health and safety. Iowaska concedes the importance of this public safety determination, *see* Pet. 21 n.12 ("recogniz[ing] the practical value of deploying DEA's subject-matter expertise to determine appropriate safety and anti-diversion protocols"), and DEA's settlement agreement with Church of the Eagle and Condor illustrates the numerous judgments DEA must make in evaluating whether and under what conditions a religious-exemption request should be granted, *see supra* pp. 25-26.

The need for that analysis also responds to the third *TRAC* factor, which asks whether "human health and welfare are at stake." 750 F.2d at 80. That factor weighs heavily against granting the mandamus relief Iowaska seeks here. Ayahuasca contains DMT, which is an "exceptionally dangerous" drug, *O Centro*, 546 U.S. at 432, and *Soul Quest* illustrates the grave public dangers ayahuasca use can present, even as part of a

religious ceremony. As one ground for denying Soul Quest's religious-exemption request for ayahuasca, DEA cited "a pending wrongful death action brought by the estate of a retreat participant against Soul Quest, alleging that after the participant took ayahuasca and kambo (frog secretions) at the retreat, he experienced adverse effects from the substances and became unresponsive." 92 F.4th at 962.

The fourth *TRAC* factor concerns "the effect of expediting delayed action on agency activities of a higher or competing priority." 750 F.2d at 80. This factor also points strongly against finding a compelling equitable ground for mandamus relief here. As explained, DEA has numerous competing demands for religious exemptions and other policy matters to consider, with very limited staff. DEA has worked diligently to respond to those competing priorities, recently granting two religious exemption requests and continuing to work on Iowaska's request. *See supra* p. 24. An agency's balancing of competing obligations is committed to agency discretion, and not the kind of agency action for which mandamus relief is appropriate. *See supra* pp. 25-26.

The fifth *TRAC* factor concerns “the nature and extent of the interests prejudiced by delay.” 750 F.2d at 80. Iowaska contends that it has held no ayahuasca sacraments since July 2019, that it has been denied tax-exempt status while its application is pending, and that it has been compelled to rent and maintain the secure facility DEA inspected without being able to use that facility for its intended purpose. Pet. 14. Those concerns do not provide compelling grounds, as a general matter, to truncate DEA’s full review of Iowaska’s religious-exemption request. And they are particularly insufficient to support mandamus relief here given that (1) Iowaska could seek an expedited response to its religious-exemption request in a district court action under the APA or RFRA, *see supra* pp. 19-21, and (2) Iowaska substantially delayed DEA’s review of its religious-exemption request by focusing on its 501(c)(3) case seeking tax-exempt status rather than timely responding to DEA’s request for additional information, *see supra* pp. 12-13.

The sixth *TRAC* factor likewise provides no support for mandamus relief. Iowaska asserts that “DEA has been far from diligent” in considering its request. Pet. 31. But, as discussed, DEA has been in frequent communication with Iowaska to provide updates and request

additional information. And DEA has actively reviewed the request to the extent consistent with the press of the agency's other obligations. Iowaska's argument also elides the fact that much of the delay here is attributable to the entity's own litigation choices. Consideration of these factors thus counsels heavily against mandamus relief in these circumstances.

Conclusion

The petition for a writ of mandamus should be denied.

Respectfully submitted,

Respectfully submitted,

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July 2025

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 5743 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Century Schoolbook 14-point font, a proportionally spaced typeface.

/s/ Lowell V. Sturgill Jr.

Lowell V. Sturgill Jr.

CERTIFICATE OF SERVICE

I hereby certify that on July 8, 2025, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

/s/ Lowell V. Sturgill Jr.

Lowell V. Sturgill Jr.

Drug Enforcement Administration
Diversion Control Division
Guidance Document

Title: Guidance Regarding Petitions for Religious Exemption from the Controlled Substances Act Pursuant to the Religious Freedom Restoration Act (Revised)

Summary: The Drug Enforcement Administration sets forth guidance, in conformance with Executive Order 13891, which will inform religious organizations which use controlled substances within the free exercise of their religion, of the process in which they may petition for an exemption from the Controlled Substances Act.

Activity: Request for religious exemptions from the Controlled Substances Act.

To Whom It Applies: Parties requesting religious exemptions from the Controlled Substances Act.

In recent years, the Drug Enforcement Administration (DEA) has seen an increase in requests from parties requesting religious exemptions from the Controlled Substances Act (CSA) to permit the use of controlled substances. The Religious Freedom Restoration Act (RFRA) provides that the "Government shall not substantially burden a person's exercise of religion" unless the Government can demonstrate "that application of the burden to the person is in furtherance of a compelling governmental interest and is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1. In *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 126 S.Ct. 1211 (2006), the Supreme Court held that government action taken pursuant to the CSA is subject to RFRA. In order to obtain an exemption under RFRA, a party must, as a preliminary matter, demonstrate that its (1) sincere (2) religious exercise is (3) substantially burdened by the CSA. 42 U.S.C. § 2000bb et seq.

The guidelines that follow are an interim measure intended to provide guidance to parties who wish to petition for a religious exemption to the CSA:

1. Filing Address. All petitions for exemption from the Controlled Substances Act under RFRA shall be submitted in writing or email to the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, ODLP@usdoj.gov.

2. Content of Petition. A petition may include both a written statement and supporting documents. A petitioner should provide as much information as he/she deems necessary to demonstrate that application of the Controlled Substances Act to the party's activity would (1) be a substantial burden on (2) his/her sincere (3) religious exercise. Such a record should include detailed information about, among other things, (1) the nature of the religion (*e.g.*, its history, belief system, structure, practice, membership policies, rituals, holidays, organization, leadership, etc.); (2) each specific religious practice that involves the manufacture, distribution, dispensing, importation, exportation, use or possession of a controlled substance; (3) the specific

controlled substance that the party wishes to use; and (4) the amounts, conditions, and locations of its anticipated manufacture, distribution, dispensing, importation, exportation, use or possession. A petitioner is not limited to the topics outlined above, and may submit any and all information he/she believes to be relevant to DEA's determination under RFRA and the Controlled Substances Act.

3. Signature. The petition must be signed by the petitioner, who must declare under penalty of perjury that the information provided therein is true and correct. *See* 28 U.S.C. § 1746.

4. Acceptance of Petition for Filing. Petitions submitted for filing are dated upon receipt by DEA. If it is found to be complete, the petition will be accepted as filed, and the petitioner will receive notification of acceptance. Petitions that do not conform to this guidance will not generally be accepted for filing. A petition that fails to conform to this guidance will be returned to the petitioner with a statement of the reason for not accepting the petition for filing. A deficient petition may be corrected and resubmitted. Acceptance of a petition for filing does not preclude DEA from making subsequent requests for additional information.

5. Requests for Additional Information. DEA may require a petitioner to submit such additional documents or written statements of facts relevant to the petition as DEA deems necessary to determine whether the petition should be granted. It is the petitioner's responsibility to provide DEA with accurate contact information. If a petitioner does not respond to a request for additional information within 60 days from the date of DEA's request, the petition will be considered to be withdrawn.

6. Applicability of DEA Regulations. A petitioner whose petition for a religious exemption from the Controlled Substances Act is granted remains bound by all applicable laws and Controlled Substances Act regulations governing registration, labeling and packaging, quotas, recordkeeping and reporting, security and storage, and periodic inspections, among other things. *See* 21 C.F.R. §§ 1300-1316. A petitioner who seeks exemption from applicable CSA regulations (as opposed to the CSA itself) may petition under 21 C.F.R. § 1307.03. Such petition must separately address each regulation from which the petitioner seeks exemption and provide a statement of the reasons for each exemption sought.

7. Activity Prohibited Until Final Determination. No petitioner may engage in any activity prohibited under the Controlled Substances Act or its regulations unless the petition has been granted and the petitioner has applied for and received a DEA Certificate of Registration. A registration granted to a petitioner is subject to subsequent suspension or revocation, where appropriate, consistent with CSA regulations and RFRA.

8. Final Determination. After the filed petition—along with all submissions in response to any requests for additional information—has been fully evaluated, the Assistant Administrator of the Diversion Control Division shall provide a written response that either grants or denies the petition. Except in the case of affirming a prior denial or when the denial is self-explanatory, the response shall be accompanied by a statement of reasons upon which the decision is based. This written response is a final determination under 21 U.S.C. § 877.

9. Application of State and Other Federal Law. Nothing in these guidelines shall be construed as authorizing or permitting any party to take any action which such party is not authorized or permitted to take under other Federal laws or under the laws of the State in which he/she desires to take such action. Likewise, compliance with these guidelines shall not be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department policies.

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